

## AMENDMENTS TO THE CLAIMS

A complete set of claims is included below, as well as the current status of each claim. This listing of claims replaces all prior versions, and listings, of claims in the application.

1. (currently amended) A computer-implemented method for assessing and managing risks associated with utilizing a pharmaceutical product comprising:

identifying, characterizing and ranking, by a processor processing device, adverse one or more events caused by using the pharmaceutical product;

identifying a medication use process associated with a pharmaceutical product, wherein the medication use process is implemented to protect patients from a risk of experiencing adverse one or more side effects associated with use of the pharmaceutical product, wherein the medication use process comprises diagnosing a medical condition of a patient, prescribing the pharmaceutical product to the patient, dispensing the pharmaceutical product to the patient, administering the pharmaceutical product and monitoring the patient;

determining, by the processor processing device, whether the medication use process will be adequate to protect patients from experiencing adverse the one or more side effects;

based on the determination, identifying potential failure modes where the medication use process will not be adequate to does not protect patients from experiencing adverse the one or more side effects and identifying one or more multiple redundant interventions for each failure mode;

automatically quantifying, by the processor processing device, the potential effect of said failure mode to create a pharmaceutical hazard score, wherein said hazard score considers the severity and frequency of occurrence of the effects of said failure;

automatically conducting, by the processor processing device, a logical hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes; and

based on the logical hazard assessment, designing a risk management intervention program to manage said adverse one or more events.

2. (original) The method of claim 1 further comprising:  
implementing said risk management program.
  
3. (original) The method of claim 2 further comprising:  
measuring the effectiveness of said risk management program.
  
4. (original) The method of claim 3 wherein measuring the effectiveness of said risk management program comprises:  
measuring and defining metrics, measurement systems, program goals, objectives and program performance analysis and reporting.
  
5. (previously presented) The method of claim 3 further comprising:  
integrating said effectiveness measurement into said pharmaceutical product hazard score.
  
6. (original) The method of claim 5 wherein the step of integrating said effectiveness measurement comprises:  
reporting said effectiveness measurement.
  
7. (currently amended) The method of claim 1 wherein the step of identifying, characterizing and ranking the adverse one or more events caused by using the pharmaceutical product comprises:  
analyzing available data from animal, toxicology, pharmacokinetic, pharmacodynamic and pharmacogenomic studies of the pharmaceutical product.
  
8. (currently amended) The method of claim 1 wherein the step of identifying, characterizing and ranking the adverse one or more events caused by using the pharmaceutical product comprises:  
analyzing existing clinical safety data for the pharmaceutical product.

9. (currently amended) The method of claim 1 wherein identifying, characterizing and ranking the ~~adverse one or more~~ events caused by using the pharmaceutical product comprises: analyzing risks identified in similar products.

10. (currently amended) The method of claim 1 wherein the step of identifying, ~~characterizing and ranking said potential~~ failure modes comprises:  
graphically depicting the medication use process of prescribing, dispensing, and administering the pharmaceutical product as a plurality of steps; and identifying subprocesses for each of said steps.

11. (previously presented) The method of claim 1 wherein identifying potential failure modes of the medication use process comprises:

identifying one or more processes of prescribing, dispensing or administering the pharmaceutical product or a combination thereof.

12. (original) The method of claim 1, wherein said pharmaceutical hazard score comprises:  
utilizing a pharmaceutical severity scale; and utilizing a pharmaceutical frequency of occurrence scale.

13. (currently amended) The method of claim 1 wherein the ~~logical~~ hazard assessment comprises:

analyzing the criticality and detectability of the failure mode to determine the need to mitigate the failure mode.

14. (currently amended) The method of claim 13 wherein the ~~logical~~ hazard assessment further comprises:

analyzing existing risk control measures for the failure mode to determine whether the existing risk control measures mitigate the failure mode without further intervention.

15. (previously presented) The method of claim 1 wherein the risk management intervention program comprises:

education, communications and/or control measures in redundant combinations and incorporating adult learning principles designed to be readily implemented in order to reduce the incidence and consequences of said failure modes.

16. (original) The method of claim 1 wherein the risk management intervention program comprises:

a primary intervention targeted to reduce the incidence of each failure mode.

17. (original) The method of claim 1 wherein the risk management intervention program comprises:

one or more redundant backup interventions to decrease the occurrence of and/or mitigate the consequences of failure of the primary intervention.

18. (original) The method of claim 1 wherein the risk management intervention program comprises:

distributing interventions to multiple end users, wherein the multiple end users are selected from the group consisting of physicians, pharmacists, health care providers, caregivers and patients.

19. (original) The method of claim 1 wherein the risk management intervention program comprises:

coordinating care among multiple end users, wherein the multiple end users are selected from the group consisting of physicians, pharmacists, health care providers, caregivers and patients.

20. (original) The method of claim 1 wherein the risk management intervention program comprises:

tailoring said risk management intervention program to local medical practice standards and needs including, but not limited to the delegation of primary responsibility for the program from physician to support staff.

21. (previously presented) The method of claim 1 wherein the risk management intervention program comprises:

designing interventions that transfer medical knowledge and reinforce knowledge retention.

22. (original) The method of claim 1 wherein the risk management intervention program comprises:

utilizing one or more of adult learning principles, enablers, personal application, multiple media, repetitive messaging, self assessments, feedback, incentives and consequence messages.

23. (original) The method of claim 1 wherein the risk management intervention program comprises:

developing a risk communication curriculum to communicate risk to an end user, wherein the end user is selected from the group consisting of physicians, pharmacists, health care providers, caregivers and patients.

24. (original) The method of claim 1 wherein the risk management intervention program comprises:

transferring know-how, insights, techniques, methods, and processes from more experienced physicians and support staff to less experienced physicians and support staff.

25. (original) The method of claim 1 wherein the risk management intervention program comprises:

utilizing existing interventions and tools developed by one or more of clinicians, peer to peer forums, clinical consultations and preceptorships.

26. (original) The method of claim 1 wherein the risk management intervention program comprises:

implementing human behavior changing interventions.

27. (original) The method of claim 1 wherein the risk management intervention program comprises:

utilizing disease management approaches, principles, methods, techniques and tools to change end user behavior.

28. (original) The method of claim 1 wherein the risk management intervention program comprises:

integrating risk messages into promotional materials of the pharmaceutical product.

29. (currently amended) The method of claim 1 wherein the risk management intervention program comprises:

utilizing a professional support network for the collection and management of data associated with the adverse one or more events.

30. (currently amended) The method of claim 29 wherein said data comprises:  
occurrences of the adverse one or more events.

31. (original) The method of claim 1 wherein the risk management program comprises:  
educational resources for delivering information regarding prescribing, dispensing, and use of the pharmaceutical product.

32. (original) The method of claim 31 wherein the educational resources comprises:  
identification of control measures for the pharmaceutical product.

33. (previously presented) The method of claim 31 wherein the educational resources comprises:
  - classes to instruct an end user on said control measures.
34. (original) The method of claim 31 wherein said educational resources are available by electronic, written, audio, or video communication.
35. (original) The method of claim 1 wherein the risk management intervention program comprises:
  - implementing distribution controls wherein said distribution controls manage the availability of the pharmaceutical product.
36. (original) The method of claim 35 wherein the distribution controls comprise:
  - limiting availability of the pharmaceutical product to a single source.
37. (original) The method of claim 35 wherein the distribution controls comprise:
  - limiting availability of the pharmaceutical product to authorized pharmacies.
38. (original) The method of claim 35 wherein the distribution controls comprise:
  - requiring a pharmacist to be certified to dispense the pharmaceutical product.
39. (original) The method of claim 35 wherein the distribution controls comprise:
  - limiting physician prescribing rights.
40. (original) The method of claim 39 wherein limiting physician prescribing comprises:
  - limiting the number of refills per prescription, limiting the expiration date of a prescription, and/or limiting the form of a prescription.

41. (original) The method of claim 1 wherein the risk management intervention program comprises:

mandating periodic or intermittent tests for the existence of contraindications for the pharmaceutical product.

42. (original) The method of claim 41 wherein said contraindications comprise pregnancy.

43. (withdrawn) A method for creating educational materials for use in mitigating the risks of a pharmaceutical product comprising:

compiling a database of educational components wherein said components are useful in providing information regarding the risks of a pharmaceutical product or procedures to mitigate said risks;

selecting a plurality of said components from said database to create an educational tool kit wherein the components are selected based on the expected effectiveness of said component in managing the identified risks of the pharmaceutical product;

tailoring interventions to assure implementation by other end users;

designing a dissemination plan for distributing the educational materials to a target audience;

implementing the dissemination plan through forums and venues, such as learning labs, virtual learning forums, and preceptorships;

evaluating the expected impact of the educational tool kit on the target audience; and

adding, deleting, or modifying the selected components to achieve a desired expected impact.

44. (withdrawn) The method of claim 43 further comprising:

integrating a measurement of actual effectiveness of said components of said educational tool kit into said database.

45. (withdrawn) The method of claim 43 wherein said database is compiled from existing risk management programs.

46. (withdrawn) The method of claim 43 wherein the target audience comprises a patient being administered the pharmaceutical product.
47. (withdrawn) The method of claim 43 wherein the target audience comprises a patient's caregiver or family member.
48. (withdrawn) The method of claim 43 wherein the target audience comprises a physician prescribing the pharmaceutical product.
49. (withdrawn) The method of claim 43 wherein the target audience comprises a physician's clinical or office staff.
50. (withdrawn) The method of claim 43 wherein the target audience comprises a pharmacist dispensing the pharmaceutical product.
51. (cancelled)
52. (cancelled)
53. (currently amended) A system, comprising:  
~~a processor processing device; and~~  
~~a computer-readable storage medium in communication with the processor processing device,~~ the computer-readable storage medium including one or more programming instructions for:  
~~identifying adverse one or more events caused by using a pharmaceutical product,~~  
~~identifying a medication use process for the pharmaceutical product, wherein the medication use process is implemented to protect patients from a risk of experiencing adverse one or more side effects associated with use of the pharmaceutical product, wherein the medication use process comprises diagnosing a medical condition of a patient, prescribing the pharmaceutical product to the patient, dispensing the pharmaceutical product to the patient, administering the pharmaceutical product and monitoring the patient,~~

determining, by the processor processing device, whether the medication use process will be adequate to protect patients from experiencing adverse one or more side effects,

based on the determination, identifying potential failure modes of the medication use process and identifying one or more multiple redundant interventions for each failure mode,

quantifying the potential effect of said failure modes to create a pharmaceutical hazard score, wherein said hazard score considers the severity and frequency of occurrence of the effects of said failure modes,

conducting a logical hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes, and

designing a risk management program to manage adverse one or more events wherein said risk management program comprises control measures to reduce the incidence and consequences of said failure modes.

54. (cancelled)

55. (withdrawn) A pharmaceutical product risk assessment and management kit comprising: one or more intervention components, wherein said one or more intervention components are selected for inclusion in said pharmaceutical product risk assessment and management kit by a pharmaceutical product risk assessment and management method.

56. (withdrawn) A pharmaceutical product risk assessment and management kit of claim 55, wherein said kit is selected from the group consisting of a patient kit, a physician kit and a pharmacist kit.

57. (withdrawn) A pharmaceutical product hazard scoring chart comprising: a first column of a pharmaceutical severity scale; and a second column of a pharmaceutical frequency of occurrence scale; wherein a pharmaceutical hazard score is the product of said first column and said second column.